

REMARKS

Entry of the foregoing and further and favorable consideration of the subject application are respectfully requested.

As correctly stated in the Official Action, Claims 1, 4, and 5 are pending in the present application. Claims 1, 4, and 5 stand rejected.

By the present amendment, Claim 1 has been amended to recite a regime or regimen for "loosening and/or relaxing" cutaneous and/or subcutaneous human skin tissue. Support for this amendment can be found, at least, in original Claim 1. Claim 1 has been amended to incorporate the subject matter of Claim 5. Claim 5 has been canceled, without prejudice to or disclaimer of the subject matter contained therein. Applicants expressly reserve the right to file a continuation or divisional application on any subject matter canceled by the present amendment. New Claims 24-31 derive support, at least, from original Claims 7-14. New Claims 32 and 33 derive support, at least, from original Claims 1, 22, and 23. Accordingly, no new matter has been added.

Rejections Under 35 U.S.C. § 112

Claims 1, 4, and 5 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite.

Claim 1 stands rejected for the recitation of "loosening/slackening." The Examiner suggests that it is unclear whether this term is read as 'and' or 'or' and that the specification

does not provide a standard for ascertaining the requisite degree. This rejection, as it applies to Claim 1 as amended, is respectfully traversed.

Without conceding to the merits of this rejection and solely in an effort to expedite prosecution, Claim 1 has been amended to recite a "loosening and/or relaxation" of cutaneous and/or subcutaneous skin tissue. Applicants respectfully submit that the requisite degree of loosening and/or relaxing is to be determined by one using the invention, based on the extent of the treatment desired by one skilled in the art or the candidate subject. Accordingly, the claim language is believed clear and definite. Withdrawal of this rejection is respectfully requested.

Claim 1 also stands rejected for the recitation of "such treatment," as allegedly lacking antecedent basis. Without conceding to the merits of this rejection and solely in an effort to expedite prosecution, Claim 1 has been amended as the Examiner has suggested. Accordingly, withdrawal of this rejection is respectfully requested.

Claim 4 stands rejected for the recitation of "for smoothing the skin," as allegedly unclear whether it further limits Claim 1. This rejection is respectfully traversed.

Applicants respectfully submit that Claim 4 recites a particular application of the regime or regimen recited in Claim 1. Applicants submit that Claim 3 of the patent that issued in the parent application (U.S. Patent No. 6,344,461) analogously recites an application for the regime or regimen for treating skin wrinkles and fine lines recited in Claim 1 of the '461 patent. In particular, Claim 3 of the '461 patent recites the use of the

regime or regimen for attenuating the microrelief of the skin. Similarly, in the present case, the meaning of Claim 4 would be readily apparent to one skilled in the art. Withdrawal of this rejection is respectfully requested.

Claim 5 stands rejected for the recitation of "muscular decontraction or relaxation," as allegedly unclear whether it further limits Claim 1. Without conceding to the merits of this rejection and solely in an effort to expedite prosecution, Claim 5 has been canceled, thereby mooting this rejection.

Rejections Under 35 U.S.C. § 102

Claims 1, 4, and 5 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Lee (U.S. Patent No. 5,569,678). The Examiner asserts that Lee *et al.* disclose a method for administering an effective amount of a calcium channel antagonist. The Examiner argues that Lee *et al.* disclose that calcium channel antagonists soften and minimize scar tissue. The Examiner concludes that although Lee *et al.* do not recite the specific end effects in the presently claimed invention, they are inherent in the process of softening or eliminating scar tissue. Claim 5 has been canceled, thereby mooting this rejection as it applies to this claim. This rejection, as it applies to Claim 1 as amended and Claim 4 and as the Examiner may deem it to apply to new Claims 24-33, is respectfully traversed.

Applicants respectfully submit that Lee *et al.* administer a calcium antagonist in order to impair calcium metabolism/transport in order to inhibit fibroblast exocytosis, to

retard biosynthesis of collagen and sulfated glycosaminoglycans, to decrease collagen content, and to stimulate collagenase activity. (Col. 3, line 66 to Col. 4, line 6). These processes contribute to the softening of scar tissue and control scar production. The present invention provides a regime or regimen for loosening or relaxing cutaneous and/or subcutaneous skin tissue via muscle decontraction or relaxation. Muscle decontraction or relaxation is disclosed or suggested nowhere in the Lee *et al.* publication. Lee *et al.* cite the overproduction of protein and collagen as leading to excessive scarring or keloid formation. (Col. 4, lines 21-25). In contrast, mechanisms such as muscle decontraction or relaxation underlie the loosening and/or relaxing of cutaneous or subcutaneous tissue in the presently claimed invention. Thus, the purpose of Lee *et al.* is to prevent molecular and/or cellular disorders due to injury rather than utilizing the mechanical process of muscle decontraction or relaxation. The end results of Lee *et al.* described in Example 5 are a softening and fading of scars, disappearance of scar contracture, reduction in scar size and shrinkage of scars. (Col. 12, lines 5-24). In particular, Applicants respectfully submit that the effects of a reduction in scar size and shrinkage of scars directly contrast with the claimed invention which achieves a loosening and/or relaxing effect on cutaneous and/or subcutaneous tissue.

Further, Applicants respectfully submit that, unlike the present invention, Lee *et al.* are administering the calcium antagonists to injured, scarred skin. In contrast, in the presently claimed invention, at least one inhibitor of at least one calcium channel is applied to the skin of a candidate subject in need of loosening and/or relaxing of the cutaneous

and/or subcutaneous skin, not skin containing scar tissue. There is absolutely no overlap of the disclosure of Lee *et al.* with the presently claimed invention.

Additionally, Applicants respectfully point out that the existence of calcium channels inside cutaneous and subcutaneous skin tissue was not determined until 1999 as disclosed in the specification on page 6, lines 9-11. Thus, neither Lee *et al.* nor one skilled in the art could have envisioned that the presently claimed invention was even possible in 1994 when Lee *et al.* filed their application. Accordingly, one skilled in the art would not have been motivated to apply the calcium antagonists to non-scared tissue, *i.e.*, cutaneous and/or subcutaneous tissue in need of loosening and/or relaxation. Thus, the presently claimed invention is not disclosed or even suggested by Lee *et al.*

Moreover, with respect to new Claims 32 and 33, Lee *et al.* do not disclose or suggest the concurrent use of a keratolytic active agent. On the contrary, a keratolytic agent causes desquamation, exfoliation, or scrubbing properties that would be contraindicated for treating injured skin. Therefore, Lee *et al.* cannot anticipate Claims 32 and 33 because the Lee *et al.* publication does not disclose or suggest all the elements of the presently claimed invention.

Rejections Under the Judicially-Created Doctrine of Obviousness-Type Double Patenting

Claims 1, 4, and 5 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over Claims 1-4 of U.S. Patent No. 6, 344,461. Claim 5 has been canceled, thereby mooting this rejection as it applies to

this claim. This rejection, as it applies to Claim 1 as amended and Claim 4, is respectfully traversed.

Applicants respectfully submit that the presently claimed invention may be utilized in other applications other than the treatment of skin wrinkles and fine lines. For instance, Claim 4 recites that the claimed regime or regimen can be used for smoothing the skin. Thus, the presently claimed invention is not obvious based on the disclosure of the '461 patent and is sufficiently distinct. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusions

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Jennifer Topmiller
Jennifer A. Topmiller, Ph.D.
Registration No. 50,435

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: November 4, 2002

Attachment to REPLY & AMENDMENT dated November 4, 2002

Marked-up Claim 1

1. (Amended) A regime or regimen for [loosening/slackening] loosening and/or relaxing cutaneous and/or subcutaneous human skin tissue via muscle decontraction or relaxation, comprising administering to a candidate subject in need of such [treatment] regime or regimen, a thus-effective amount of at least one inhibitor of at least one calcium channel.